DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 08678/S-028

**SUPPLEMENT APPROVAL**

Sandoz, Inc.
Attention: Richard Almond
Associate Director Regulatory Affairs
4700 Sandoz Drive
Wilson, NC 27893

Dear Mr. Almond:

Please refer to your Supplemental New Drug Application (sNDA) dated January 13, 2016, received, January 13, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ISONIAZID Tablets USP, 100 mg and 300 mg.

This "Changes Being Effected" supplemental new drug application provides for:

- Addition of "toxic epidermal necrolysis" and "drug reaction with eosinophilia syndrome (DRESS)" to the **ADVERSE REACTIONS** section under subsection **Hypersensitivity Reactions** and "pancreatitis" to the **ADVERSE REACTIONS** section under subsection **Gastrointestinal Reactions**
- Updates to the **CLINICAL PHARMACOLOGY** section under subsections **Mechanism of Action**, **Resistance**, and **Microbiology** regarding resistance mutations and in vitro susceptibility methods
- Updates to the **REFERENCES** section
- Updates to the **HOW SUPPLIED** section with product NDC numbers
- Updates to the **DESCRIPTION** section
- Revisions to the Carton and Container labels to display larger font for middle 4 NDC numbers

## APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for

industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 08678/S-028**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, M.D., M.P.H.
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SUMATHI NAMBIAR
07/13/2016